

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

MYLAN PHARMACEUTICALS, INC.,	:	
ROCHESTER DRUG CO-OPERATIVE,	:	
INC., MEIJER, INC., MEIJER	:	
DISTRIBUTION, INC., AMERICAN	:	
SALES COMPANY, LLC, WALGREEN	:	
CO., SAFEWAY INC., SUPERVALU INC.,	:	
and HEB GROCERY CO. LP, et al.,	:	
	:	
Plaintiffs,	:	Civ. No. 12-3824
	:	CONSOLIDATED
	:	
v.	:	
	:	
WARNER CHILCOTT PUBLIC	:	
LIMITED COMPANY, et al.,	:	
	:	
Defendants.	:	
	:	

**DEFENDANT WARNER CHILCOTT’S REPLY IN SUPPORT OF ITS MOTION TO
EXCLUDE THE DECLARATION AND TESTIMONY OF JEFFREY LEITZINGER**

CONTAINS CONFIDENTIAL–ATTORNEYS’ EYES ONLY INFORMATION

**FILED UNDER SEAL PURSUANT TO PROTECTIVE ORDER FOR
CONFIDENTIAL DISCOVERY MATERIAL DATED OCTOBER 1, 2012 (ECF No. 86)**

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INTRODUCTION

When a plaintiff bases its request for class action status on the opinion of an expert, the plaintiff bears the burden to establish that the expert's proposed testimony is reliable, will assist the trier of fact, and is aligned with the complaint that brought the plaintiff into court.¹ Direct Purchaser Plaintiffs fail to establish any of those things here.

Plaintiffs' responses to the arguments asserted in Warner Chilcott's motion to exclude Dr. Leitzinger's testimony fail to cure the fatal flaws in the expert's proposed testimony:

- Plaintiffs' contention that *Daubert simply does not apply* at this stage ignores the Third Circuit's *Hydrogen Peroxide* decision, many cases since that decision, and the basic requirements of Rule 702 that an expert's testimony assist the trier of fact and be based on "reliable principles and methods."
- Plaintiffs inappropriately seek to defer consideration of, or ignore altogether, "*merits*" issues that expose Dr. Leitzinger's opinions as unreliable.
- Dr. Leitzinger's reliance on counsel's "*overcharge*" label for his damages analysis ignores economic reality and does not describe this case. The expert's unquestioning willingness to use an "overcharge" label even though *two different products* are being compared—contrary to his economic judgment—informs his entire analysis and renders it unreliable.
- Dr. Leitzinger ignores stark evidence that significant numbers of the 23 potential class members were *not impacted* by Defendants' alleged conduct, potentially including some of the three large national wholesalers who account for over 95% of Doryx direct purchases.² This evidence reveals individual inquiries that make class certification inappropriate, but Leitzinger avoids the evidence altogether.
- Plaintiffs inappropriately *change their theory of the case* (from seeking damages for an "overall scheme" and each alleged "product switch" to disavowing any damages claim except for one related to the launch of tablets outside the statute of limitations period, in 2005). Plaintiffs are the "masters of their complaint" but should be forced to live with that complaint.
- Dr. Leitzinger fails to justify the *assumptions* on which his impact and damages analyses "are conditioned."

¹ See, e.g., *Comcast Corp. v. Behrend*, 133 S. Ct. 1426, 1433 (2013); *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 147 (1999); *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 592 (1993).

² Ordover Decl. ¶ 19 (ECF No. 247).

- Dr. Leitzinger admits his model cannot account for likely, lawful Doryx competition that would affect impact and damages and concedes the model would need to be *corrected*—which he has not done but promises to address some day.
- Dr. Leitzinger confirms that his model is capable of calculating only an *aggregate damages pool*, conceding his approach flies in the face of *Comcast*. He does not propose a methodology capable of calculating any class member’s individual damages in a formulaic way.

Plaintiffs cannot overcome these defects merely by pointing to other readily distinguishable decisions in which courts have declined to exclude Dr. Leitzinger’s opinion, which is primarily what Plaintiffs have done in their opposition memorandum. This Court should exclude Dr. Leitzinger’s testimony, opening declaration, and rebuttal declaration³ under Federal Rule of Evidence 702 and *Daubert*.

ARGUMENT

I. As the Supreme Court Has Confirmed, *Daubert* Applies Fully at the Class Certification Stage, and This Case Shows Why

Direct Purchaser Plaintiffs begin their argument opposing Warner Chilcott’s motion with the meritless assertion that “[it] is questionable whether *Daubert* applies to expert testimony regarding class certification.” DPP *Daubert* Opp. at 7 (ECF No. 334). But *all* of the decisions Plaintiffs cite predate the Third Circuit’s decision in *In re Hydrogen Peroxide*, which held that “weighing conflicting expert testimony at the certification stage is not only permissible; it may be integral to the rigorous analysis Rule 23 demands.” *See* 552 F.3d 305, 323 (3d Cir. 2008) (holding that District Court erred by not resolving expert dispute as it related to predominance requirement and vacating class certification order).

Courts have held that the rigorous analysis required at the class certification stage requires a full *Daubert* review. *See, e.g., In re Chocolate Confectionary Antitrust Litig.*, 289

³ Dr. Leitzinger’s unauthorized and untimely rebuttal report also should be stricken for the reasons set forth in Warner Chilcott’s July 1, 2013 letter in support of its motion to strike. (ECF No. 343.)

F.R.D. 200, 208 (M.D. Pa. 2012) (holding that “a thorough *Daubert* analysis is appropriate at the class certification stage of this MDL in light of the court’s responsibility to apply a ‘rigorous analysis’ to determine if the putative class has satisfied the requirements of Rule 23.”); *Sher v. Raytheon Co.*, 419 Fed. App’x 887, 890–91 (11th Cir. 2011) (finding Seventh Circuit approach persuasive and reversing district court’s certification of class where it did “not determine[] facts, from the often conflicting evidence, sufficient to determine whether class certification is or is not appropriate.”); *Am. Honda Motor Co. v. Allen*, 600 F.3d 813, 815-16 (7th Cir. 2010) (“We hold that when an expert’s report or testimony is critical to class certification, . . . a district court must conclusively rule on any challenge to the expert’s qualifications or submissions prior to ruling on a class certification motion.”); *Unger v. Amedisys*, 401 F.3d 316, 323 n.6 (5th Cir. 2005) (“In order to consider Plaintiffs’ motion for class certification with the appropriate amount of scrutiny, the Court must first determine whether Plaintiffs’ expert testimony supporting class certification is reliable.”); *Neale v. Volvo*, Civ. No. 2:10–cv–4407, 2013 WL 784962, at *2 (D.N.J. Mar. 1, 2013) (holding that under *Comcast*, an analysis under *Daubert* likely applies at the class certification stage, but even if plenary *Daubert* review is not required, under Federal Rules of Evidence 403 and 702 court was required to consider admissibility of expert testimony, and granting motion to exclude expert testimony).

The need for rigorous scrutiny of the expert testimony on which class certification may be based is all the more important after the Supreme Court’s recent ruling in *Comcast v. Behrend*. 133 S. Ct. 1426, 1435 (2013) (rejecting plaintiffs’ economic expert’s damages model and reversing order approving class certification); *see also, e.g., Hydrogen Peroxide*, 552 F.3d at 316 n.15 (Unlike a Rule 12(b)(6) motion to dismiss, “an order certifying a class usually is the district judge’s last word on the subject; there is no later test of the decision’s factual premises.”)

(quoting *Szabo v. Bridgeport Machs., Inc.*, 249 F.3d 672, 675–76 (7th Cir. 2001)). In *Comcast*, the Supreme Court rejected the Third Circuit’s approach—advanced by Plaintiffs here—that the court should defer testing the admissibility of a class certification expert’s testimony to the “merits phase.” DPP Daubert Opp. at 8 (“[I]t would be wrong to evaluate Dr. Leitzinger’s class declaration as if it were supposed to be a final merits report, which it is not . . .”). As the Court held in *Comcast*, “[b]y refusing to entertain arguments against [plaintiffs’] damages model that bore on the propriety of class certification, simply because those arguments would also be pertinent to the merits determination, the [Third Circuit] ran afoul of our precedents requiring precisely that inquiry.” 133 S. Ct. at 1432–33.

Plaintiffs’ attempt to shield Dr. Leitzinger’s testimony from serious scrutiny should be rejected, and this Court should exclude the testimony as unreliable under *Daubert*.

II. The “Merits” Issues Plaintiffs Complain about Bear Directly on Class Certification

Plaintiffs respond to the showing Warner Chilcott made to rebut Dr. Leitzinger’s opinions by arguing that the evidence does not relate to “class maintainability.” DPP Class Cert. Reply at 7 (ECF No. 336) (“[A]ll of the evidence Warner Chilcott assembles” about its improvements to Doryx “is common to the class rather than individual to its members.”). But Defendants’ showing relates directly to class certification. And Dr. Leitzinger’s failure to address these facts is one of the major reasons his proposed testimony is unreliable, unhelpful, and should be excluded.

Dr. Leitzinger’s conclusions that impact and damages can be shown formulaically ***depend on*** his assumption that the new Doryx products were “not product improvements,” and on that basis he assumes that Warner Chilcott never would have launched any tablet form of Doryx (unscored 75 mg tablet, unscored 100 mg tablet, scored 75 mg tablet, scored 100 mg

tablet, single-scored 150 mg tablet, double-scored 150 mg tablet, single-scored 200 mg tablet, or any other new version). Leitzinger Decl. ¶ 26. Based on that assumption, among others, Dr. Leitzinger assumes that doxycycline hyclate DR competition would have been frozen in time since 2005, with all competitors selling only capsules, and with assumed average prices lower than they are today. Having simplified the world in this way, Dr. Leitzinger is able to conclude that most class members would have been impacted and suffered damages as a result of Defendants' conduct. Leitzinger Decl. ¶ 28; Leitzinger Reb. Decl. ¶¶ 7-8.

Dr. Leitzinger admits that his conclusions are based on this assumption (and his assumption regarding the generic entry, discussed below): “[M]y opinions regarding impact and overcharges *are conditioned upon* those assumptions.” Leitzinger Reb. Decl. ¶ 10 (emphasis added). Therefore, evidence showing the benefits of the new versions of Doryx (*see* WC Class Cert. Opp. (Direct) at 6–16, 47 (ECF No. 233)) exposes as baseless any assumption that Warner Chilcott would not have launched *any* of the new versions of Doryx that it launched in the real world. Defendants' showing on these issues is not only relevant to class certification, but it also confirms that Dr. Leitzinger—who simply assumes this evidence does not exist and never attempts to rebut it—has no reliable methodology to determine classwide impact or damages.

Plaintiffs have the burden to establish a plausible but-for world against which to compare the real world, and Dr. Leitzinger's proposed testimony is incapable of doing that. *See, e.g., Sterling Merchandising, Inc. v. Nestle, S.A.*, 656 F.3d 112, 120–21, 126 (1st Cir. 2011) (affirming summary judgment for lack of standing, where plaintiff used “unrealistic and speculative economic forecast . . . as its but-for scenario”); *In re New Motor Vehicles Canadian Export Antitrust Litig.*, 632 F. Supp. 2d 42, 45 (D. Me. 2009) (granting summary judgment where plaintiff failed to establish that every proposed class member in fact was injured by paying

higher transaction prices than he/she would have paid without the anticompetitive action; holding, “plaintiffs are unable to prove causation (sometimes called antitrust impact) by the method of proof they have chosen”); *Kelley v. Microsoft Corp.*, No. C07–0475 MJP, 2009 WL 413509, at *6, 8 (W.D. Wa. 2009) (decertifying class where plaintiffs relied on evidence “based on presumptions which cannot establish [consumer protection act] causation”); *Allied Orthopedic Appliances, Inc. v. Tyco Healthcare Group L.P.*, 247 F.R.D. 156, 165–66 (C.D. Cal. 2007) (denying certification where, among other things, plaintiffs relied on example documents to establish but-for world, rather than conducting any meaningful market analysis).

III. Direct Purchaser Plaintiffs May Not Call Lost Profits Damages an “Overcharge” to Justify Class Certification and to Preserve Their Expert’s Conclusions

A. Dr. Leitzinger Cannot Reasonably Describe the Alleged Injury Here as an “Overcharge”

Dr. Leitzinger’s conclusions regarding classwide impact and damages are based on an assumption, without analysis, that any injury to direct purchasers took the form of an “overcharge” (*i.e.*, paying too much) and not lost profits (*i.e.*, the impact on a direct purchasing reseller—like Rochester Drug, ASC, or Meijer—of having to buy and resell more expensive tablets instead of hypothetically less expensive capsules). Leitzinger Decl. ¶¶ 27–28; Leitzinger Reb. Decl. ¶¶ 5–8. And “Plaintiffs agree with Warner Chilcott that if Plaintiffs sought lost profits, that would make a major difference in how class certification would be judged here.” DPP Class Cert. Reply at 3. Plaintiffs justify their “overcharge” label by declaring that they are the “masters of their complaint” and “are free to choose the damages theory they want to pursue.” DPP Daubert Opp. at 15–16.

But the Supreme Court has held that, at the class certification stage, the court must take a close look at what the case will look like when it is tried to determine if the case fairly can

proceed on behalf of a class of plaintiffs. *See, e.g.*, Fed. R. Civ. P. 23(b)(3)(D); *Wal-Mart Stores, Inc. v. Dukes*, 131 S. Ct. 2541, 2558–59 (recognizing that Rule 23(b) requires the court to make findings with respect to predominance and superiority of the case proceeding as a class action before permitting class certification); *In re Hydrogen Peroxide*, 552 F.3d at 317 (recognizing that courts “consider the substantive elements of the plaintiffs’ case in order to envision the form that a trial on those issues would take”). It is true that a plaintiff may file a complaint calling its injury what it wishes to call it, but at the class certification stage the court must investigate how that injury will be proven at trial, and in particular whether the proof of impact and damages at trial will vary by class member. *See Powers v. Lycoming Engines*, 272 F.R.D. 414, 426 (E.D. Pa. 2011) (“The superiority analysis assesses the advantages and disadvantages of using the class-action device in relation to other methods of litigation. . . . It requires a rigorous analysis as to how potential relief to individual class members would be managed, ‘specifying, for example, the methodology by which calculations and awards of relief would be made with respect to individual class members.’”) (quoting *Hohider v. United Parcel Serv.*, 574 F.3d 169, 202 (3d Cir. 2009)); *Lloyd v. Gen. Motors Corp.*, 266 F.R.D. 98, 105–07 (D. Md. 2010) (“[T]he Court must mentally dress rehearse the trial proposed by the parties,” including “the anticipated proof, the jury instructions, the verdict sheet, and the burdens imposed on the jury.”); *see also Johnston v. HBO Film Mgmt.t, Inc.*, 265 F.3d 178, 194–95 (3d Cir. 2001) (affirming denial of class certification motion where manageability problems at trial would be too severe for case to proceed as a class action).

Here, as discussed more fully in Warner Chilcott’s opposition to Direct Purchaser Plaintiffs’ class certification motion, calculating Direct Purchaser Plaintiffs’ potential injury as an “overcharge” makes no sense. WC Class Cert. Opp. (Direct) at 30–37. Direct Purchaser

Plaintiffs are not patients or consumers of pharmaceutical products; they are pharmaceutical distributors that purchase and resell the products they purchase for a profit. WC Mem. in Support of Mot. to Dismiss at 4 (describing proposed class representatives) (ECF No. 84). If these plaintiffs are worse off because they purchased and resold one product instead of a different, less expensive product (to which they can apply a greater percentage markup⁴), how is the difference in prices an “overcharge” in the price of one of the products? It is not. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

As discussed in Warner Chilcott’s opening brief in support of its *Daubert* motion, Dr. Leitzinger’s testimony about the use of a lost profits versus “overcharge” analysis were made in the context of a hypothetical example in which—as alleged here—a plaintiff (auto dealer) loses the opportunity to purchase (and resell) less expensive cars due to some anticompetitive conduct:

[REDACTED]

[REDACTED] (emphasis added). But change the example from Porsches and Hyundais to Hondas and Hyundais—or any other variation—and the result would be the same. The acquisition and resale prices for the auto

⁴ [REDACTED]

dealer may be closer between the two cars, but no economist reasonably would call the price difference an “overcharge” in the price of the Honda, [REDACTED]

For all their reliance on prior cases to suggest that Dr. Leitzinger’s opinions and assumptions have been accepted by other courts (except when they have not been, *see infra* Section V), Plaintiffs ignore that **no court** has ever held that, where plaintiffs were purchasers of different, non-AB-rated-equivalent pharmaceutical products, an overcharge analysis applies. And in the only possible exception (*TriCor*), the court improperly deferred judgment on this issue to a future “merits” phase, an approach now barred by *Comcast*. *See Teva Pharm. USA, Inc. v. Abbott Labs.* (“*TriCor*”), 252 F.R.D. 213, 228 (D. Del. 2008) (“declin[ing] to address the merits at this [class certification] stage”).⁵

An expert’s damages methodology must be consistent with economic reality. *See ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 290 (3d Cir. 2012) (“In an antitrust case, an expert opinion generally must ‘incorporate all aspects of the economic reality’ of the relevant market.”) (quoting *Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1057 (8th Cir. 2000)); *Craftsmen Limousine, Inc. v. Ford Motor Co.*, 363 F.3d 761, 777 (8th Cir. 2004) (holding that expert opinion should not have been admitted because it failed to account for economic reality);

⁵ *Lower Lake Erie* and *Lee-Moore Oil* are not to the contrary. DPP Daubert Opp. at 19. In neither case did the court consider the issue of whether an overcharge or lost profits methodology should apply. Moreover, in *Lower Lake Erie*, the plaintiff steel companies were end-users of the transportation services at issue and were not reselling them to others, as the Direct Purchaser Plaintiffs are here. *In re Lower Lake Erie Iron Ore Antitrust Litig.*, 998 F.2d 1144, 1154 (3d Cir. 1993). For those end-user steel companies, other than a price comparison between the price paid for the defendants’ services and the price of alternative services, no other damages measure was possible. That is materially different from the situation here, where the true injury to the reseller plaintiffs is determined by the value of the alleged lost opportunity to buy and resell less expensive drug products. And *Lee-Moore Oil* did not involve an “overcharge” analysis being applied to different products, as Plaintiffs propose here, but instead involved two different sellers of gasoline, a product that could not be more fungible. *Lee-Moore Oil Co. v. Union Oil Co. of California*, 599 F.2d 1299, 1300–01 (4th Cir. 1979) (addressing per se Sherman Act violation where, unlike here, court presumed competitive injury). As such, the use of an “overcharge” theory in *Lee-Moore Oil* says nothing about the propriety of such a theory here, where the products being compared are different forms of a drug that are not AB-rated equivalents.

Total Containment, Inc. v. Dayco Products, Inc., No. Civ. A. 1997-CV-6013, 2001 WL 1167506, at *5 (E.D. Pa. Sept. 6, 2001) (excluding expert's damages opinion and concluding that assumptions used were "not based upon the 'realities of the market'") (citing *Concord Boat*, 207 F.3d at 1056). Here, Dr. Leitzinger's use of an "overcharge" damages measure is divorced from economic reality. It was given to him by Plaintiffs' counsel and reflects no analysis, let alone economic expertise. [REDACTED]

[REDACTED] WC Daubert Mem. (Leitzinger) at 8–9.

B. Dr. Leitzinger Ignores Significant Evidence Showing Large Numbers of Direct Purchaser Class Members Suffered No Impact at All from the Alleged Conduct

By blindly relying on counsel's "overcharge" label, Dr. Leitzinger ignores substantial evidence showing that a significant share of potential class members suffered no impact at all—and in fact benefited from Defendants' alleged conduct. WC Class Cert. Opp. (Direct) at 36–41.

1. Dr. Leitzinger Ignores Generic Bypass

[REDACTED] members of the proposed Direct Purchaser Class that purchased and resold branded Doryx *before* generic entry *did not* purchase and resell branded or generic Doryx (or purchased less of it) *after* generic entry. Those class members were "bypassed" by retailers who purchased the generic version directly from the manufacturer instead of the purported class member. In these cases, the proposed class member did not suffer any injury from the alleged delay in generic entry. [REDACTED]

⁶ Warner Chilcott's opposition to Direct Purchaser Plaintiffs' class certification motion cited data produced by Defendant Mylan establishing the existence of generic bypass with respect to sales of generic Doryx by Mylan. WC Class Cert. Opp. (Direct) at 36–37. The testimony cited below comes from depositions taken after Warner Chilcott filed its class certification opposition brief and opening brief in support of its *Daubert* motion on May 16, 2013.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

What is Dr. Leitzinger’s response to this phenomenon and the critique by Defendants’ expert, Professor Ordovery, that Dr. Leitzinger failed to account for it?

This claim rests entirely on [Prof. Ordovery’s] argument that harm should be measured as lost profits in this case, which, as explained above, I understand to be wrong.

Leitzinger Reb. Decl. ¶ 18. With this convenient “understanding” from counsel, Dr. Leitzinger is able to avoid this stark evidence—showing potential class members, representing large

percentages of the proposed class, that *were not injured at all*—without any analysis. But the evidence is devastating to Dr. Leitzinger’s conclusions here, for two main reasons.

First, it establishes definitively that an “overcharge” measure makes no sense here, as even class members who paid a nominal “overcharge” under Plaintiffs’ approach suffered no impact from the alleged conduct. Thus, any analysis based on counsel’s “overcharge” label is unreliable and not helpful in determining whether Rule 23 is satisfied. *Second*, this evidence underscores that Dr. Leitzinger’s superficial analysis of “classwide” impact and damages is simply wrong. In each of the cases above, the proposed member of the Direct Purchaser Class was better off in a brand-only marketplace. And, if this case reaches trial, then the only way to determine which class members were bypassed, and to what extent, will involve *individual determinations* for each class member. That Dr. Leitzinger ignores this issue altogether, relying on a label instead of analysis, is another reason his testimony must be excluded.

2. Dr. Leitzinger Ignores Cost-Plus Pricing

Similarly, Dr. Leitzinger ignores the existence of “cost-plus” and similar contracts that show that certain potential class members would not have suffered impact from the alleged conduct—a phenomenon that is relevant regardless whether an “overcharge” or lost profits approach is used. WC Class Cert. Opp. (Direct) at 38–41. As with the generic bypass problem, in the case of cost-plus contracts, determining whether a class member sold branded or generic Doryx under a cost-plus contract involves an individualized inquiry rendering class certification inappropriate.

Dr. Leitzinger fails to address this problem in either his opening or rebuttal declaration.

_____, _____, _____ several proposed class members sold

branded or generic Doryx under a contract providing for a price based on a fixed percentage off the class member's cost, such that the class member would not necessarily have been injured—and, depending on an individualized review, may have benefited—by a delay in generic entry:

█ [REDACTED]

█ [REDACTED]

█ [REDACTED]

█ [REDACTED]

█ [REDACTED]

█ [REDACTED]

█ [REDACTED]

█ [REDACTED]

█ [REDACTED]

Warner Chilcott filed its class certification opposition brief and opening brief in support of its *Daubert* motion on May 16, 2013.

[REDACTED]

As discussed in Warner Chilcott’s opposition to Direct Purchaser Plaintiffs’ class certification motion, cost-plus pricing is an exception to the general rule prohibiting defendants from using a pass-on defense. WC Class Cert. Opp. (Direct) at 38. Potential class members (like McKesson, Cardinal, and ABC) who price at cost-plus or cost-minus are vulnerable to a pass-on defense and may not have claims for those purchases. *See Illinois Brick*, 431 U.S. at 735–36; *Hanover Shoe*, 392 U.S. at 494; *see also Kansas v. UtiliCorp United, Inc.*, 497 U.S. 199, 217–18 (1990). That may be the case even if the contract does not call for the purchase of a fixed quantity—if, for example and as here, the evidence suggests the class member would have sold more branded than generic units. WC Class Cert. Opp. (Direct) at 38–40. Determining the applicability of the cost-plus exception for any given class member is another individualized inquiry ignored by Dr. Leitzinger.

IV. Direct Purchaser Plaintiffs Cannot Use One Theory to Survive a Motion to Dismiss and a Second, Inconsistent Theory to Save Their Expert’s Opinions and Get a Class Certified

A. Direct Purchaser Plaintiffs’ Inappropriately Attempt to Amend Their Complaint in the *Daubert* and Class Certification Briefing

In an attempt to salvage Dr. Leitzinger’s opinion and artificially simplify the case to justify class certification, Direct Purchaser Plaintiffs were forced to change their theory of the case. To survive dismissal on the pleadings, Plaintiffs cast a wide net and pled a broad “overall scheme” to monopolize. DPP Compl. ¶¶ 1. Plaintiffs alleged that this overall scheme, and each alleged product switch within it, caused damages to the proposed Direct Purchaser Class. DPP Compl. ¶¶ 1-6, 55–84, 99–101. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Similarly, in response to Defendants’ argument in support of their motions to dismiss on statute of limitations grounds—*i.e.*, that claims regarding all or most of Defendant’s alleged conduct, and especially the launch of a tablet form in 2005, were time-barred—Plaintiffs argued that their “allegations also charge misconduct as part of the ongoing scheme within the limitations period, *i.e.*, when, in 2011, the defendants again reformulated Doryx through introduction of the dual-scored tablet.” DPP Summary Submission in Response to Defs.’ 12(b)(6) Mots. at 45–46 (ECF. No. 92) (“And in this case the episodes of challenged misconduct cannot fairly be considered in isolation. It is the cumulative effect of all the misconduct that forecloses or delays competition for Doryx generics.”); DPP Opp. to MTD at 48 (ECF. No. 112) (alleging Defendants’ “ongoing scheme continued into the limitations period, when, in 2011, Defendants again reformulated Doryx through introduction of the dual-scored tablet. The overcharge damages caused thereby are unquestionably recoverable.”).

But Plaintiffs’ “overall scheme” theory raised many questions about how to construct an appropriate “but-for world” in which impact and damages could be determined in a formulaic way. As Warner Chilcott discussed in its opening brief in support of its motion to exclude Dr. Leitzinger’s testimony, Plaintiffs’ case was so complicated that Plaintiffs’ own expert could not account for all the possible damages scenarios it created. WC Daubert Mem. (Leitzinger) at 19–21. And as Dr. Leitzinger has now conceded, his methodology is incapable of assessing impact and damages if any one of the alleged product switches is determined by the Court or the jury to

be lawful. Leitzinger Reb. Decl. ¶ 13 n.23 (admitting that model would need to be “adjusted”—but failing to make those adjustments—to be able to account for the possibility of any lawful competition by Warner Chilcott in the sale of Doryx tablets).

Confronted with this disabling complexity, Direct Purchaser Plaintiffs have changed course. They now seek to amend their Complaint through the *Daubert* and class certification briefing to ***no longer seek damages*** for all of the alleged product switches. “Instead, Plaintiffs seek damages solely from Defendants’ switch from 75/100 mg Doryx capsules to 75/100 mg Doryx tablets” in 2005. DPP Class Cert. Reply at 4; DPP Opp. at 22. Plaintiffs are silent about how such a simplified damages claim based on conduct eight years ago can survive in light of the Clayton Act’s four-year statute of limitations, or how evidence about the subsequent alleged switches—which took place ***after*** the 2005 tablet launch and which therefore cannot be relevant to issues such as intent or “pattern and practice”—have any role in this case at all.

But Plaintiffs’ cannot simply mold their class certification expert’s opinion to justify certification in a way that is disconnected from their Complaint. The Supreme Court recently made clear in *Comcast* that, “at the class certification stage (as at trial), any model supporting a plaintiff’s damages case ***must be consistent with its liability case***, particularly with respect to the alleged anticompetitive effect of the violation.” 133 S. Ct. at 1433 (citations omitted) (emphasis added); *see also, e.g., Gen. Electric Co. v. Joiner*, 522 U.S. 136 at 146 (upholding lower court’s exclusion of expert testimony because there was “too great an analytical gap between the data [the expert relied on] and the opinion proffered.”); *Fashion Boutique of Short Hills v. Fendi USA, Inc.*, 314 F.3d 48, 60 (2d Cir. 2002) (excluding expert in part because in making calculations, expert assumed policy that never existed); *Baker v. Urban Outfitters, Inc.*, 254 F. Supp. 2d 346, 354 (S.D.N.Y. 2003) (granting motion to exclude proffered expert report and

testimony, finding expert's opinion to be irrelevant where expert calculated damages based on benchmark not at issue in the case).

B. Direct Purchaser Plaintiffs' Cannot Run from the Supreme Court's *Comcast* Decision by Changing Their Case Theory in the *Daubert* and Class Certification Briefing

Direct Purchaser Plaintiffs try to distinguish *Comcast* by arguing that, unlike the “four theories” involved there, “Dr. Leitzinger calculates damages under a *single* theory of impact,” focusing on the launch of 75 and 100 mg Doryx tablets and discontinuance of 75 and 100 mg Doryx capsules. DPP *Daubert* Opp. at 5 (emphasis in original). But Dr. Leitzinger's approach is indistinguishable from the rejected expert's approach in *Comcast*. In *Comcast*, the plaintiffs alleged damages based on four scenarios, the court narrowed the scenarios down to one, and the plaintiffs' expert improperly proposed a methodology that did not distinguish between individual scenarios. *Comcast*, 133 S. Ct. at 1431 (rejecting damages methodology of plaintiffs' expert, who calculated damages in the aggregate and “did not isolate damages resulting from any one of the [four] theor[ies] of antitrust impact”).

Similarly here, Direct Purchaser Plaintiffs filed (and pursued discovery) with a complaint challenging a “series” of product changes, each one alleged to cause damage. *See, e.g.*, DPP Compl. ¶¶ 1, 56–84 (“first predatory product change,” “second set of predatory product changes,” etc.); *cf.* Mylan Compl. ¶¶ 52–75 (“first market switch,” “second market switch,” “third market switch,” etc.). Facing a *Daubert* challenge and class certification opposition, Plaintiffs try to narrow the case—like the District Court did in *Comcast*—and disavow seeking damages for all but one product change. But like the expert in *Comcast*, Dr. Leitzinger proposes a class certification damages methodology that calculates damages in the aggregate and does not back out damages related to the discarded theories. Leitzinger Reb. Decl. ¶13 (admitting

damages method would need to be “adjusted” to account for other product changes). Dr. Leitzinger’s approach therefore is very much like the approach rejected in *Comcast*.

* * * *

Direct Purchaser Plaintiffs’ last-minute amendment to their Complaint to survive a *Daubert* challenge should be rejected. Plaintiffs’ earlier allegations and arguments were judicial admissions, and Plaintiffs should be held to those admissions—and the resulting consequences for their experts’ opinions and class certification. *See, e.g., Berkeley Inv. Group, Ltd. v. Colkitt*, 455 F.3d 195, 212 n.20 (3d Cir. 2006).

V. Dr. Leitzinger’s Expert Opinions Must Be Rejected under *Daubert* Because His Assumptions about the But-For World Reflect No Expertise and Are Unreliable

Dr. Leitzinger responds to Warner Chilcott’s attacks on his assumptions by arguing that it is standard for economists to rely on assumptions regarding liability and the but-for world. Leitzinger Reb. Decl. ¶ 9. Warner Chilcott does not contest that a class certification expert may assume liability, but the Supreme Court in *Comcast* and other courts have held that experts may not assume the conditions of the but-for world without “kicking the tires” and independently evaluating them. Here, Dr. Leitzinger assumes the conditions of the but-for world without any analysis or investigation (citing a single Mayne document, which requires no economic expertise to read), his analysis has no content, and therefore Plaintiffs cannot show that the expert’s “scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue.” Fed. R. Evid. 702.

Plaintiffs claim that “nowhere” does Warner Chilcott argue that Dr. Leitzinger’s improper assumptions “undermine [his] key conclusion: that Plaintiffs are capable of proving common impact . . . with common evidence.” Opp. Mem. at 4. That is false. Warner Chilcott argued several times that, once the assumptions were removed, Dr. Leitzinger’s conclusions

could not hold. *See, e.g.*, WC Daubert Mem. (Leitzinger) at 6 (“Here, Dr. Leitzinger’s opinion concerning classwide impact and damages is built entirely on the assumptions provided by counsel—assumptions that he made no attempt to verify.”). Indeed, Dr. Leitzinger conceded that fact himself: “[M]y opinions regarding impact and overcharges are conditioned upon those assumptions.” Leitzinger Reb. Decl. ¶ 10.

Plaintiffs also argue that “flaws in [an expert’s] assumptions are addressed at summary judgment or trial.” Opp. Mem. at 4.⁸ But empty and unreasonable assumptions such as those made by Dr. Leitzinger are directly relevant to admissibility under *Daubert*. *See, e.g., Meadows v. Anchor Longwall & Rebuild, Inc.*, 306 Fed. App’x 781, 790 (3d Cir. 2009) (“expert testimony based on assumptions lacking factual foundation in the record is properly excluded”); *Oddi v. Ford Motor Co.*, 234 F.3d 136, 155 (3d Cir. 2000) (expert opinion based on “subjective belief or unsupported speculation” is unreliable); *Arista Records LLC v. Usenet.com, Inc.*, 608 F. Supp. 2d 409, 424, 428–29 (S.D.N.Y. 2009) (“An expert who simply regurgitates what a party has told him provides no assistance to the trier of fact through the application of specialized knowledge.”). Dr. Leitzinger’s testimony has been rejected before based on improper assumptions devoid of analysis, as here. *See Blades v. Monsanto Co.*, 400 F.3d 562, 570 (8th Cir. 2005) (“Simply put, plaintiffs presume class-wide impact without any consideration of whether the markets or the alleged conspiracy at issue here actually operated in such a manner so

⁸ Plaintiffs also misstate the *Daubert* standard in arguing that Warner Chilcott has the “Heavy Burden of Proving That Dr. Leitzinger’s Assumptions Were ‘So Unrealistic’ That They Were Made ‘In Bad Faith.’” DPP Daubert Opp. at 27 (citing *National Commc’ns Ass’n v. AT&T*, 1998 U.S. Dist. LEXIS 3198, at *152 (S.D.N.Y. Mar. 16, 1998); *Boucher v. U.S. Suzuki Mot. Corp.*, 73 F.3d 18, 21 (2d Cir. 1996); *Orson Inc. v. Miramax Film Corp.*, 983 F. Supp. 624, 635 (E.D. Pa. 1997)). But the cases Plaintiffs cite do not support any form of “bad faith” standard and do not support Plaintiffs’ position. *National Communications* was decided before *Kumho Tire* and therefore was interpreting the rules when *Daubert* did not even apply explicitly to non-scientific experts. *Boucher*, also pre-*Kumho Tire*, mentions the “bad faith” language Plaintiffs cite but also provides that an expert’s opinions can be stricken when “speculative or conjectural,” as is the case here. *Boucher*, 73 F.3d at 21. And *Orson* makes no mention of a “bad faith” standard and instead concludes that expert testimony can be excluded when based on “speculation or conjecture” and when it would not be helpful to the jury, as is also the case here. *Orson*, 983 F. Supp. at 635.

as to justify that presumption. Dr. Leitzinger *assumes* the answer to this critical issue and plaintiffs, in turn, have asked the Court to rely on this *conclusion* as support for class certification.”); *Royal Serv., Inc. v. Goody Prods., Inc.*, 865 F.2d 1271, 1989 WL 1725, at *2 (9th Cir. Jan. 6, 1989) (rejecting Dr. Leitzinger’s conclusory testimony); *Sample v. Monsanto Co.*, 218 F.R.D. 644, 652 (E.D. Mo. 2003) (District Court in *Blades*) (“Plaintiffs did not meet their burden of establishing the necessary elements of Rule 23(b)(3) through the testimony of Dr. Leitzinger, whose ‘assumptions,’ ‘presumptions’ and ‘conclusions’ fall far short of actually *establishing* antitrust impact on a class-wide basis through common proof.”).

Dr. Leitzinger also fails to justify the specific assumptions on which his conclusions depend, as discussed below.

A. Dr. Leitzinger Fails to Justify His Implausible and Unreliable Assumption that in the But-For World Competition Would Have Been Frozen for All Time at Capsules

Dr. Leitzinger does nothing to justify his reliance on the incredible assumption that Warner Chilcott never would have launched another form of Doryx after 2005.

First, he never addresses the existence of Warner Chilcott’s ‘161 patent. *See* Leitzinger Dep. Tr. 52:14–53:12 (Ex. 29); WC Daubert Mem. (Leitzinger) at 14–15; WC Class Cert. Opp. at 45–46 (citing *Warner Chilcott Labs. Ireland, Ltd. v. Impax Labs., Inc.*, 2012 WL 1551709, at *3 (D.N.J. Apr. 30, 2012)). It is implausible and improper to assume without analysis that Warner Chilcott would have walked away from that investment rather than incorporate it into a new tablet or capsule product that lawfully would have excluded competition, as in the real world. [REDACTED]

[REDACTED]

Second, Dr. Leitzinger never addresses the substantial showing by Warner Chilcott to rebut this assumption, including the expert declaration of Dr. Guy Webster. Dr. Webster's declaration showed that each new version of Doryx offered clear benefits to patients and doctors, benefits that translated into substantial adoption of the new versions—even when lower cost generic copies were available—and additional sales for Warner Chilcott. Webster Decl. (ECF No. 237). Dr. Leitzinger simply assumes away these benefits.

Nor do Plaintiffs come forward with any contrary showing to rebut Dr. Webster's conclusions. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

9 [REDACTED]

10 [REDACTED]

[REDACTED] This evidence and similar evidence further confirms the fatal deficiencies in Dr. Leitzinger's but-for world based on his blind assumption that Warner Chilcott never would have had a reason to launch tablets in the but-for world. Where an expert ignores relevant evidence in favor of assumptions, that is where the protections of *Daubert* are most needed.

B. Dr. Leitzinger Cannot Justify His Implausible and Unreliable Assumption that Several Generics Would Have Entered Early in the But-For World

As Heather Bresch, the CEO of Mylan, testified in this case:

[REDACTED]

[REDACTED] Yet Dr. Leitzinger concludes that generic manufacturing, regulatory approval, and product launch processes can be assumed without analysis. As discussed below, Plaintiffs misconstrue the standard by which Dr. Leitzinger's assumption of early generic entry should be judged and mischaracterize the evidence relating to potential generic competition.

First, Plaintiffs argue that Dr. Leitzinger was not required to perform any assessment of when generic competitors could have launched generic Doryx capsules in the but-for world, candidly admitting that such an assessment "would require expertise regarding FDA regulations and pharmaceutical marketing that Dr. Leitzinger does not possess." DPP Class Cert. Reply at 6. But even if Dr. Leitzinger lacks the expertise personally to test his assumptions, he should have "kicked the tires" just as he would have in an academic setting. Nor do Plaintiffs come forward with any support from experts with qualifications like Dr. Jasti's or Dr. Webster's to shore up Dr. Leitzinger's conclusions. But that does not remove the responsibility from Dr. Leitzinger to perform a reliable analysis.

As discussed in Warner Chilcott’s opening brief, courts have held that experts have a duty to “kick the tires” on the assumptions underlying their opinions. *Soldo v. Sandoz Pharm. Corp.*, 244 F. Supp. 2d 434, 530 (W.D. Pa. 2003); *Shannon v. Hobart*, No. 09–5220, 2011 WL 442119, at *3 (E.D. Pa. Feb. 8, 2011); *see also Fashion Boutique of Short Hills*, 314 F.3d at 60. Without any independent check on the basis for an assumption forming the basis for an expert’s conclusion, the conclusion is simply “subjective belief or unsupported speculation” prohibited by *Daubert*. *Elcock v. Kmart Corp.*, 233 F.3d 734, 745–46 (3d Cir. 2000).

The Third Circuit has made it clear that “the reliability analysis [required by *Daubert*] applies to ***all aspects*** of an expert’s testimony: the methodology, the facts underlying the expert’s opinion, [and] the link between the facts and the conclusion.” *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 291 (3d Cir. 2012) (quoting *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 155 (3d Cir. 1999)). “In some circumstances, an expert might be able to rely on the estimates of others in constructing a hypothetical reality, but to do so, the expert must explain why he relied on such estimates and must demonstrate why he believed the estimates were reliable.” *Id.* at 292. The Third Circuit has rejected the very argument being made by Plaintiffs here that reliance on internal business documents as “assumptions” is *per se* reasonable and immune from inquiry into the reasonableness of those assumptions. *Id.* (“However, there is no *per se* rule of inclusion where an expert relies on a business plan; district courts must perform a case-by-case inquiry to determine whether the expert’s reliance on the business plan in a given case is reasonable.”). As stated by the Third Circuit in *ZF Meritor*, Plaintiffs’ “suggestion that the reasonableness of an expert’s reliance on facts or data to form his opinion is somehow an inappropriate inquiry under Rule 702 results from an unduly myopic interpretation of Rule 702 and ignores the mandate of *Daubert* that the district court must act as a gatekeeper.” *Id.* at 294.

Second, Dr. Leitzinger failed to kick the tires of his assumption about generic competition. [REDACTED]

[REDACTED] Dr. Leitzinger's reliance on this document illustrates how his opinions cannot survive the strict standards set forth by the Third Circuit. Dr. Leitzinger has not conducted or described any investigation into who prepared the document, the methodology used by the creator, the "qualifications of the individuals who prepared the document, or the assumptions on which the estimates were based." *ZF Meritor*, 696 F.3d at 292. Moreover, counsel for Direct Purchaser Plaintiffs traveled to Adelaide, South Australia to take the deposition of a former Mayne employee, [REDACTED]

[REDACTED] Plaintiffs' counsel had ample opportunity to examine the witness on the circumstances surrounding the creation of this forecast. Yet Plaintiffs ended the deposition in under three and a half hours without any questioning related to this document. It is inconceivable that this lack of investigation or inquiry into the "assumptions" made by Dr. Leitzinger would survive scrutiny in an academic setting, which only underscores the unreliability of Dr. Leitzinger's conclusions. Plaintiffs cannot avoid investigating the "facts" relied upon by Dr. Leitzinger and then hide behind his opinions by declaring them to be based on reasonable assumptions.

Moreover, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] WC Class Cert. Opp. (Direct) at 48–56. Dr. Leitzinger failed to do any of this analysis.

Finally, Plaintiffs mischaracterize Warner Chilcott’s opposition by contending that the “sole basis” for the critique of Dr. Leitzinger’s assumptions is the declaration of Dr. Bhaskara Jasti. DPP Class Cert. Reply at 36. As discussed above and in the opposition to Plaintiffs’ class certification motion, Warner Chilcott challenges Dr. Leitzinger’s assumption based on substantial document discovery (including from the files of the generics about which Dr. Leitzinger makes his assumptions) and expert testimony (including from Prof. Ordovery and Dr. Webster) in addition to Dr. Jasti’s declaration. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

¹¹ [REDACTED]

¹² [REDACTED]

Leitzinger neglected that evidence in assuming generic entry dates, and his opinions therefore are unreliable.

VI. Dr. Leitzinger's Promise to "Adjust" His Model in the Future Cannot Salvage His Class Certification Expert Report Now

In his rebuttal declaration, Dr. Leitzinger argues that he can "adjust" his methodology if it turns out that he is wrong about (1) what competition would look like in but-for world (§ 13) or (2) sales volumes in the but-for world (§ 22). But the need for these changes to his methodology confirm what Warner Chilcott argued in its opening brief: Dr. Leitzinger's proposed methodology is an inadequate basis for class certification, is unreliable, and should be excluded.

And the promised adjustments would not fix anything. *First*, the assumption about competition in the but-for world forms the basis for Dr. Leitzinger's conclusion that Direct Purchaser Plaintiffs would have paid lower prices for capsules than they paid in the real world for tablets. Dr. Leitzinger assumes *all* of the new versions of Doryx were illegal and *none* of them would have been launched in the but-for world. But for every one of them that the Court or the jury finds to be lawful (*i.e.*, if Plaintiffs fail to carry their burden to show that the anticompetitive effects of a new version outweighed the procompetitive benefits), the effects of that competition will need to be quantified and eliminated from the damages calculation. For example:

- If the Court or the jury determines that the launch of scored tablets was lawful, then Plaintiffs may not recover damages for any impact on the prices paid or volumes purchased by class members *due to that lawful competition*, whether in the form of scored 75 mg, 100 mg, or 150 mg tablets.
- If the Court or the jury determines that the launch of higher dosage strengths was lawful, then Plaintiffs may not recover damages for any impact on the prices paid or volumes purchased by class members *due to that lawful competition*.
- If the Court or the jury determines that Warner Chilcott's '161 Patent would have allowed Warner Chilcott to launch a new capsule product in 2005 that would have

benefited from the exclusivity that valid patent conferred, then Plaintiffs may not recover damages for any impact on the prices paid or volumes purchased by class members *due to that lawful competition*.

Dr. Leitzinger's proposal of [REDACTED]

[REDACTED] for individual kinds of tablets Warner Chilcott may launch cannot account for these possibilities and all their variations. Leitzinger Reb. Decl. ¶ 13 n.23. Determining if a given purchase by a proposed class member in one of these scenarios would have gone to Warner Chilcott or hypothetical generic competitor is not something Dr. Leitzinger's program—original or adjusted—can achieve. Similarly, even if the class member would have purchased the generic, would the price have been low enough to allow an expert to identify an “overcharge” in the price of the branded product? If so, what portion of the “overcharge” was caused by Defendants' conduct, and what portion was the result of lawful competition from a scored product or greater dosage strength tablet? Dr. Leitzinger's program—original or adjusted—cannot answer those questions either.

Comcast requires that “a model purporting to serve as evidence of damages in [a] class action must measure *only* those damages attributable to that theory. If the model does not even attempt to do that, it cannot possibly establish that damages are susceptible of measurement across the entire class for purposes of Rule 23(b)(3).” 133 S. Ct. at 1433 (emphasis added). Expressing concerns similar to those above regarding Dr. Leitzinger, the Supreme Court held that the plaintiffs' expert's model in *Comcast* could not justify certifying a class:

But such assurance [that damages will not require labyrinthine individual calculations] is not provided by a methodology that identifies damages *that are not the result of the wrong*. For all we know, cable subscribers in Gloucester County may have been overcharged because of petitioners' alleged elimination of satellite competition (a theory of liability that is not capable of classwide proof); while subscribers in Camden County may have paid elevated prices because of petitioners' increased bargaining power vis-a-vis content providers (another theory that is not capable of

classwide proof); while yet other subscribers in Montgomery County may have paid rates produced by the combined effects of multiple forms of alleged antitrust harm; and so on.

Id. at 1434 (emphasis added).

Second, with respect to Dr. Leitzinger's failure to propose a methodology to determine but-for sales volumes properly, this is another fatal error, not a parameter to "adjust." Leitzinger Reb. Decl. ¶ 22. Dr. Leitzinger's assumed sales volumes in the but-for world are the same as real world sales of the branded product before generic entry. Ordoover Decl. ¶ 61. But that fails to account for the decrease in sales following the termination of promotion by Warner Chilcott, which Dr. Leitzinger himself assumes would occur after generic entry. *Id.* ¶ 63. Here again, the promise to adjust his model only highlights the fatal deficiencies of Dr. Leitzinger's proposed opinions.

Finally, Dr. Leitzinger's promised adjustments raised many new questions that neither Plaintiffs nor Dr. Leitzinger answer. For example, Dr. Leitzinger promises that, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Leitzinger Reb. Decl. ¶ 13 n.23. But Dr. Leitzinger never identifies what documents he would use to support these calculations, whether such documents exist, what other drugs he may consider as benchmarks, or how he would select them. He also promises to [REDACTED]

[REDACTED] *Id.* But he provides no explanation of how he would perform that calculation.

These are some of the reasons the Supreme Court held in *Comcast* that an expert must do more than merely promise to determine damages and injury at some point in the future. *Comcast*, 133 S. Ct. at 1433. Deferring the hard questions that come with actually defining a reliable model cannot satisfy Rule 702 or *Daubert*. WC Daubert Mem. (Leitzinger) at 23–25.

VII. Dr. Leitzinger’s Aggregate, Fluid Recovery Damages Model Will Not Assist the Trier of Fact and Must Be Rejected under *Daubert*

In response to the clear authority, including from this Court, cited in Warner Chilcott’s opening memorandum concerning the impropriety of calculating only a “pot of damages” to be sorted out later, Plaintiffs double-down on their “fluid recovery” model. They argue that under *Comcast* they must calculate only “classwide damages,” which they interpret to mean an aggregate amount of damages for the class as a whole. DPP Class Cert. Reply at 62–67. But *Comcast* requires that plaintiffs’ expert come forward with a formulaic method to determine if each class member in fact was injured, and to what extent, by the alleged conduct. *Comcast*, 133 S. Ct. at 1433 (requiring that “individual *damages calculations*” not “overwhelm issues common to the class” and that “*damages* are susceptible of measurement *across the entire class*”) (emphasis added). Dr. Leitzinger’s model cannot meet that standard, and Plaintiffs’ expert disclaims any obligation to do so. Leitzinger Reb. Decl. ¶ 6 (“Plaintiffs’ burden with respect to damages, at least as I understand it, goes no further than establishing the aggregate amount of overcharges incurred by the Class.”).

Recent cases interpreting *Comcast* confirm that a damages model that does not even attempt to show how damages to class members could be determined is insufficient and inevitably would lead to the “labyrinthine” individual damages calculations the Supreme Court warned about. See *Martin v. Ford Motor Co.*, No. 10–2203, 2013 WL 3328231, at *21–22 (E.D. Pa. July 2, 2013) (rejecting plaintiff’s expert’s proposed damages model and denying

certification for two of the proposed classes because individual questions regarding calculation of damages prevented plaintiffs from meeting predominance requirement); *Cowden v. Parker & Assoc., Inc.*, No. 5:09–323–KKC, 2013 WL 2285163, at *6 (E.D. Ky. May 22, 2013) (relying on *Comcast* and denying certification because damages calculation required individualized inquiries that overwhelmed common questions); *Forrand v. Federal Exp. Corp.*, No. CV 08–1360 DSF (PJW), 2013 WL 1793951, at *5 (C.D. Cal. Apr. 25, 2013) (denying class certification in light of *Comcast* because “the need for individualized fact inquiries dominates the determination of liability and damage issues”).

VIII. Plaintiffs’ Misuse of the Evidentiary Record Cannot Cure Dr. Leitzinger’s Failures

While Plaintiffs criticize Warner Chilcott for citing “merits” documents—which undercut one of the key assumptions underlying Dr. Leitzinger’s analysis (*supra* Section II)—Plaintiffs break their own rule by arguing merits issues that have nothing to do with class certification. Plaintiffs mis-cite and mischaracterize the evidence.

For example, Plaintiffs argue that the FDA asked Warner Chilcott to continue selling Doryx capsules after it launched its tablet products and that Warner Chilcott’s discontinuance of capsules somehow ignored an FDA mandate. DPP Class Cert. Reply at 27. But the evidence Plaintiffs chose not to cite is clear that the facts are just the opposite. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Similarly, Direct Purchaser Plaintiffs' misleading use of the evidence is clear in their discussions of documents to support their argument that the Doryx improvements were launched only as "an anti-generic strategy." DPP Class Cert. Reply at 23. As an initial matter, neither Dr. Leitzinger nor Plaintiffs' counsel identify any documents explaining how a strategy to beat competitors would be exclusionary or could violate the antitrust laws. [REDACTED]

[REDACTED]

¹³ [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Plaintiffs' counsel had ample opportunity to explore the meaning of phrases and documents with various Mayne witnesses. Yet in the vast majority of Mayne depositions and with the vast majority of Mayne documents, Plaintiffs' counsel simply asked the witness if counsel had read an excerpt of the document correctly and stayed away from questions that would explain the meaning or provide context for the assumptions their expert is making.¹⁵

¹⁴ [REDACTED]

¹⁵ [REDACTED]

CONCLUSION

For the foregoing reasons and those set forth in Warner Chilcott's opening memorandum, this Court should exclude the proposed testimony and declarations of Dr. Leitzinger under Rule 702 and *Daubert*.

Dated July 11, 2013

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CERTIFICATE OF SERVICE

I, Jack E. Pace III, hereby certify that on July 11, 2013, I caused true and correct copies of Defendant Warner Chilcott's Reply in Support of Its Motion to Exclude the Declaration and Testimony of Jeffrey Leitzinger to be served by electronic mail upon all counsel of record.

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